

TITLE OF THE ABSTRACT: To Compare the Safety and Efficacy of Sub-conjunctival application of Sponges Soaked in Mitomycin-C (MMC:0.02%) to that of Direct Injection of Mitomycin-C (MMC:0.02%) into the Sub-conjunctival Space in Trabeculectomy or Phacotrabeculectomy: A Randomized Controlled Trial

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OBJECTIVES: To Compare safety and efficacy of sub-conjunctival application of sponges soaked in Mitomycin-C (MMC:0.02%) to that of direct injection of MMC (0.02%) into the sub-conjunctival space in trabeculectomy or phacotrabeculectomy.

METHODS: In this RCT, 74 patients diagnosed with POAG, CACG or PEXG were randomized into two groups; group 1 received 0.02% MMC-soaked sponges, group 2 received sub-conjunctival injection of 0.02% MMC. Primary outcome was mean IOP, and secondary outcome measures were bleb morphology according to Indiana Bleb Appearance Grading Scale and AS-OCT, post-operative use of 5-Fluorouracil, rate of complications. Outcome measures were compared at 1 week, 1 and 3 months post-operatively. Success was

defined as ≥ 30 mmHg reduction in IOP without use of AGM. All the analysis was done using STATA /IC 15.0 software.

RESULTS: In group 1 mean preoperative IOP was 29.38 ± 8.17 and 13.51 ± 4.62 mmHg at 3 months ($p < 0.001$) and for group 2 were 30.89 ± 9.35 and 13.82 ± 3.88 mmHg respectively ($p < 0.001$). Success was 86.49% and 90.91% in sponge and injection group respectively ($p = 0.562$). Both groups achieved diffuse, shallow, less vascularized blebs at 3 months (p value = 0.5235, 0.9880, 0.3173 respectively). Complication rates were similar across both groups. Subconjunctival MMC injection is an effective, safe, convenient and time saving alternative to sponge soaked delivery of MMC in trabeculectomy/ phacotrabeculectomy.

KEYWORDS: Trabeculectomy, Phacotrabeculectomy, Mitomycin-C, Primary open angle glaucoma, Angle closure glaucoma, Pseudoexfoliation glaucoma, Sponge soaked method, Sub-conjunctival injection, Intraocular pressure, Indiana Bleb Appearance Grading Score, Anterior segment OCT.